

Serial No.: 10/591,737
Atty. Docket No.: P71419US0

REMARKS

The Office Action mailed December 2, 2009, has been carefully reviewed and, by this Amendment, Applicants have canceled claims 8, 14 and 20-28, amended claims 1-7, 9-13 and 15-19, and added claims 29-36. Claims 1-7, 9-13, 15-19 and 29-36 are pending in the application. Claims 1, 9 and 15 are independent.

As an initial matter, Applicants have amended the abstract for greater conformity with U.S. practice. No new matter has been added.

The Examiner stated that the present application includes claims directed to two groups of inventions, namely Group I, claims 1-13 and 15-28; and Group II, claim 14, which groups were stated as not being so linked as to form a single general inventive concept under PCT Rule 13. 1. A provisional election was made by the Applicants' undersigned representative on November 29, 2009, to prosecution the invention of Group I. This provisional election is hereby affirmed. Furthermore, claim 14 has been canceled. Applicants expressly reserve the right to refile claim 14 as well as the other claims canceled herein in this or a subsequent application.

The Examiner provisionally rejected claims 1-4, 7-13, 15, 16, 20-22 and 24-26 on the ground of non-statutory obviousness-type

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double patenting as being unpatentable over claims 1-14 of copending application, Serial No. 10/549,567.

With the amendments set forth herein, 1-4, 7-13, 15, 16, 20-22 and 24-26 are patentable over claims 1-14 of copending application, Serial No. 10/549,567. As set forth in each of independent claims 1, 9 and 15, the presently claimed invention includes an inner bag liner with spiral-shaped folding lines formed by compacting the bag lengthwise while twisting the bottom of the bag relative to the rim. This structure prevents pancaking of the inner bag liner, the advantages of which are representatively described in the specification, among other places, on page 1, lines 18-22 and page 5, line 29 to page 6, line 2; page 6, lines 11-18; and page 11, lines 26-30. Favorable reconsideration of the amended claims and withdrawal of the provisional double patenting rejection is therefore requested.

The Examiner objected to claim 23 as containing an informality, and rejected claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 23 and 27 have been canceled herein.

The Examiner rejected claims 1-6, 8-12, 15-26 and 28 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,591,144 to Smith et al. ("Smith").

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As set forth in independent claim 9 as amended herein, the present invention is directed to an ostomy appliance including an adhesive wafer, a receiving member and inner bag liner. The adhesive wafer has a first hole for receiving a stoma, ureter, or catheter, and a first surface to be attached to the wearer's abdomen, back, or chest. The receiving member is attached to the adhesive wafer and has a second hole for receiving wastes exiting the stoma, ureter or catheter. The disposable inner bag liner is positioned inside the receiving member and is releasably attachable to the adhesive wafer by a first coupling element. The disposable inner bag liner has an open end with a third hole for receiving wastes exiting the stoma, ureter or catheter and a closed end opposite the open end that forms a bottom part of the liner when the liner is unfolded. The first coupling element is in the form of an adhesive flange projecting from a rim of the third hole and has a surface for releasable sealing against a first surface of the adhesive wafer. When the inner bag liner is assembled, it is compacted in a lengthwise direction while the closed end is rotated relative to the open end to twist the bag liner.

Through twisting while the liner is being compacted, spiral shaped folding lines are defined which serve to avoid "pancaking" of the bag (see page 6, lines 11-18 of the specification). The "pancaking" phenomenon is especially seen when

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the present invention is used with colostomies as the output in such cases comprises very little water (i.e., where the viscosity of the output is high). When pancaking occurs, the result is that the output will adhere to the top of the bag and not fall into the bag (see page 18, lines 18-21).

The pancaking problem is avoided by the folded and twisted configuration of the inner bag liner which creates the spiral-shaped folding lines. More particularly, by providing an inner bag liner which, in its compacted state, is twisted about its length direction such that spiral shaped folding lines are formed, the bottom of the inner bag liner is arranged to be so close to the stoma that output from the stoma will initially contact the liner bag bottom. Once the output is in contact with the inner bag liner, the gravity of the output will cause the inner bag liner to unfold and also untwist, with gravity ultimately causing the bottom of the liner to move into its lowest possible position inside the receiving member. This twisting and compacting of the inner bag liner to create spiral-shaped folding lines thus ensures that the sides of the liner are only exposed to the wastes after the lower part of the bag has been filled, thereby reducing the risk that the sides of the liner will adhere to one another (see page 5, line 29 to page 6, line 2). This folded structure is not shown or suggested by Smith.

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Smith discloses a drainage bag including an outer bag 1 and an inner bag or liner 2. The liner 2 is fully extended within the outer bag at all times, with the two bags being manufactured as a unit in which the openings of both bags are thermo-welded to a flange 3. Hence, there is nothing in Smith to suggest that the inner bag could have a folded configuration prior to use and that the liner would then be unfolded as wastes entering the bag during use apply pressure against the bottom portion of the inner bag liner which is adjacent the liner hole in the folded configuration.

Further, Smith is unlike the present invention in that the receiving member of the present invention (i.e., the outer bag) is configured to be reused when the used inner bag liner has been disposed of, by applying a new inner bag liner to the same receiving member. In Smith neither the inner nor the outer bag are configured to be reused (see Smith, column 2, lines 36-48 and column 5, lines 23-41). As a result, since in Smith the outer bag is not reused by insertion of a new inner bag liner therein, there is no reason to have the inner bag liner in a folded configuration prior to use. On the contrary, the manufacturer of the Smith ostomy appliance would naturally provide the inner liner in the fully inserted and unfolded state, as shown in Smith, in order to avoid any problems that could be associated with the process of unfolding the inner bag. Hence, there is nothing in Smith to

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suggest any desirability for modifying the disclosed configuration of the inner bag, in which the inner bag is already in a fully extended orientation, to instead include a *folded* inner bag liner with spiral-shaped folding lines that is unfolded only during use of the bag as claimed by the present invention.

Still further, Smith provides no solution to the problem to which the present invention is directed. On the contrary, there is nothing in Smith to even hint that the problem of pancaking was recognized or even contemplated. And, in fact, the inner bag liner according to Smith would suffer from the pancaking problem with a highly viscous output from the stoma as such output would cause the sides of the inner bag liner to adhere to each other such that the "pancaking" phenomenon would arise.

Finally, in response to the Examiner's statement that "the inner bag liner of Smith would be capable of having spiral lines in its compacted position", Applicants again point out that Smith does not show or suggest that the inner bag liner thereof is or should ever be in a compacted, let alone twisted, orientation. And there is certainly nothing in the wholly disposable construction of Smith that would suggest any benefit to lengthwise compaction in combination with a twisting of the liner as claimed by the present invention. Rather, the only suggestion for the

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compacted inner liner with spiral-shaped folding lines of the presently claimed invention is Applicants' own invention.

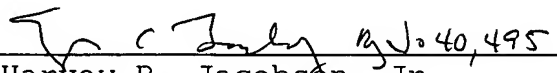
For at least the foregoing reasons, claim 9 is patentable over the prior art. Favorable reconsideration thereof, as well as the claims dependent thereon, is requested.

Claims 1 and 15 as amended herein is also in condition for allowance for the same reasons as claim 9. Favorable consideration and allowance of claims 1 and 15, and the claims dependent thereon, is requested.

With the foregoing amendments and remarks, the application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By  No. 40,495
for Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
Telephone: (202) 638-6666
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HBJ:SCB